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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,204	07/31/2003	James E. Selis	1142-001	2183
25215 7590 01/25/2008 DOBRUSIN & THENNISCH PC 29 W LAWRENCE ST SUITE 210 PONTIAC, MI 48342			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 01/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/631,204

Applicant(s)

SELIS, JAMES E.

Examiner

Melanie Tyson

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-80 is/are pending in the application.
- 4a) Of the above claim(s) 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to Applicant's amendment received on 24 January 2007.

Claim 80 remains withdrawn from consideration as being drawn to a non-elected species (see action dated 06 March 2007).

Claim Objections

1. Claims 61, 63, 67, 76-78, and 79 are objected to because of the following informalities: the contain typographical errors. In claim 61 (lines 10 and 13), replace "projects" with --project--. In claim 63 (line 1), replace "arcuate portions" with --arc segments--. In claims 67 and 76-79, replace "arcuate wire" with --arc--. In claim 77 (lines 2, 4, and 5), replace "devise" with --device--, "form" with --from--, "arcuate" with --arc--, "itself" with --themselves--, and insert the term --state-- between the phrases "their relaxed" and "and engage tissue." In claims 78 and 79 replace "unfolds" with --unfold--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant

failed to disclose the coating on the clip may comprise a low friction material. Therefore, the subject matter recited in claim 75 is considered new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

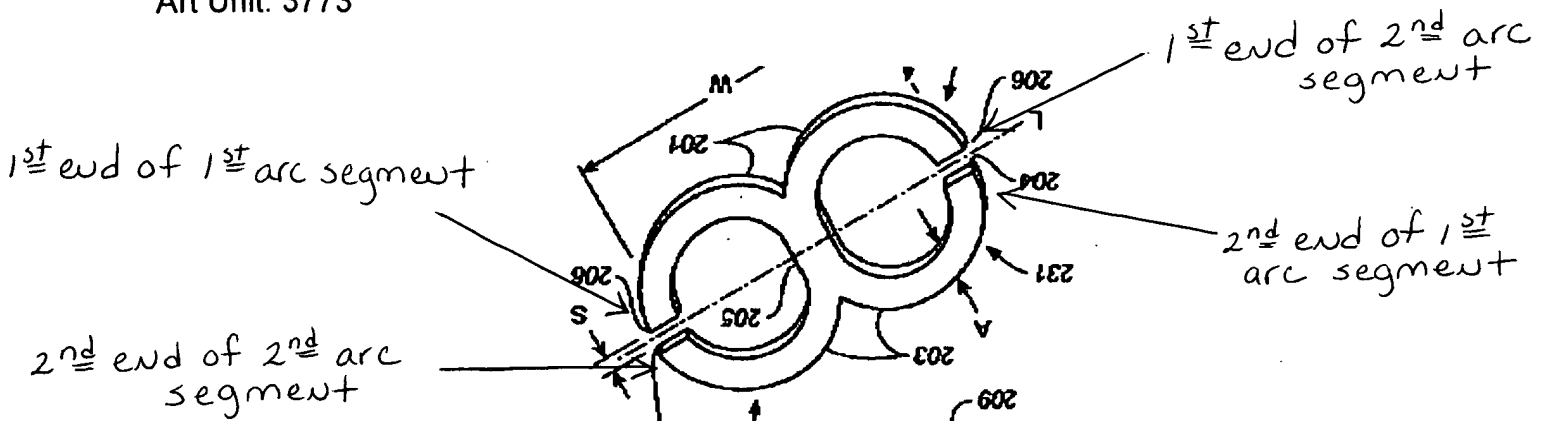
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is directed towards the paragraph "the first ends of the first and second arc segments projects in a direction away from the second ends of the first and second arc segments with respect to the clip axis." It is unclear what is meant by the phrase "with respect to the clip axis." Appropriate correction is required.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 61-63, 65, 66, 69-72, 76, and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Ainsworth et al. (2002/0165561 A1). Ainsworth discloses a clip (see entire document) consisting essentially of a first arc segment, a second arc segment, and an apex as claimed, wherein the first and second arc segments include a substantially continuous radius, are formed of a single memory shape wire, form two continuous sinusoidal shapes, are symmetrical, are coplanar, and are self-unfolding (see illustration below):



Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 64, 68, 78, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ainsworth et al.

With respect to claim 64, Ainsworth fails to disclose first and second arc segments are formed of separate wires. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the first and second

arc segments out of separate wires, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

With respect to claim 68, Ainsworth fails to disclose the diameter of the clip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the clip with a diameter of less than 5 mm, since it has been held that where the general conditions of a claimed are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. Furthermore, such a modification would have involved a mere change in size of the clip. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to claims 78 and 79, Ainsworth fails to disclose the angle at which the ends unfold with respect to the apex. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the first ends to unfold at least 45 degrees or at least 60 degrees with respect to the apex, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

8. Claims 67 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ainsworth et al. in view of Voegele (6,425,903 B1). Ainsworth discloses a device as described above, however, fails to disclose the clip further includes a barb and a coating. Voegele discloses a clip (see entire document). Voegele teaches the clip can be coated with agents to lower friction, stop bleeding, or accomplish any other desired effect. Additionally, Voegele teaches the legs of the clip may include barb-like features that could increase the holding strength, migration resistance, and imaging ability of the

marker (for example, see column 8, lines 30-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the clip of Ainsworth with a coating and barbs as taught by Voegelé.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoyns et al. (Patent No. 6,766,186 B1) disclose a post biopsy tissue marker (Figure 14). It is noted that the first ends (66) of the first (61) and second (62) arc segments project in a direction *towards* the second ends (66) of the first (61) and second (62) arc segments, therefore, Hoyns et al. does not read on claim 61. Phillips et al. (2003/0033006 A1) disclose a device for piercing tissue, however, fails to disclose first and second arc segments having first ends projecting in a direction away from the second ends (Figures 3-6). Anson Medical LTD. (WO 00/07506) discloses a device for piercing tissue, however, fails to disclose first and second arc segments having first ends projecting in a direction away from the second ends (Figure 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Melanie Tyson *MT*
December 12, 2007


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER